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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,413	04/19/2001	Marco Falciani	203970US6PCT	5932
22850	7590	07/28/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			BASICHAS, ALFRED	
		ART UNIT	PAPER NUMBER	
		3749		

DATE MAILED: 07/28/2004

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

MAILED

JUL 28 2004

GROUP 3700

Application Number: 09/807,413
Filing Date: April 19, 2001
Appellant(s): FALCIANI ET AL.

Gregory J. Maier
Registration No. 25,599
Surinder Sachar
Registration No. 34,423
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal Brief filed May 24, 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the Brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the Brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the Brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the Brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the Brief is correct.

(6) *Issues*

The appellant's statement of the issues in the Brief is correct.

(7) *Grouping of Claims*

The rejection of claims 6-25 stand or fall together because appellant's Brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) *ClaimsAppealed*

The copy of the appealed claims contained in the Appendix to the Brief is correct.

(9) *Prior Art of Record*

4,550,825	SUTRYN	11-1985
5,257,986	HERBERT	11-1993
3,647,386	GILFORD	3-1972

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 6-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutry (4,550,825) or Herbert (5,257,986) and further in view of Gilford (3,647,386). Sutry and Herbert disclose a hermetically sealed polyolefin bag for preserving and transporting a soluble sterile product in powder form and for reconstituting in the bag a ready to use solution with a predetermined concentration of the sterile product. Sutry and Herbert do not specifically state

that the water should only be added to a volume less than the capacity of the bag. Adding less than the full capacity of the bag in order to allow for room to shake is well within the knowledge and ability of one of ordinary skill in the art; it is a simple matter of common sense. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided for only filling the bag with less than the capacity of the bag or 1.5 to 2 times the volume of the ready to use solution into the inventions of Sutry and Herbert in order to provide room to shake the contents of the bag. Further as regards the claimed range, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have incorporated the claimed range into the invention disclosed by the above mentioned combination, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Sutry and Herbert further fail to specifically recite removal in plural doses. Gilford discloses a hermetically sealed polyolefin bag for preserving and transporting sterile medication specifically for removal in plural doses. This type of arrangement and method is notoriously well known in the art for the purpose of sampling the contents by removing separate doses. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated removal in plural doses, as taught by

Gilford, into the inventions disclosed by Sutry and Herbert, for the purpose of sampling the contents of the bag.

(11) Response to Argument

In the following discussion the sequence follows that established by appellants' Appeal Brief. However, headings have been inserted to indicate the issues discussed for the convenience of the reader.

Prior art bags contain sterile powder

In reference to claims 6 and 9, appellants assert the prior art does not teach that the bag "contains an amount of the sterile product in powder form" (as recited in claim 6). On page 6, 9th line, appellants' Brief contains the phase "bag itself" inferring that the scope of the claims was intended to be limited to the arrangement illustrated by figure 3 of the instant application. This is further emphasized by appellants' assertion that the prior art does not teach the claimed invention because the powder of Sutry and Herbert is stored in a separate compartment. In response, it is asserted that it would be readily apparent from a cursory glance at the illustrations of Sutry and Herbert that the compartments mentioned by appellants constitute a part of the bag and thereby contained therein. Further, nowhere in the claims is there any restriction to

compartmentalization of the bag. And, it should be noted that claim 6 does not limit the scope to "the bag itself originally contains the sterile product in powder form" as asserted by appellants on page 7, 2nd line, of the Brief.

Prior art powder placed in bag before solvent

In reference to claim 9, appellants further assert the prior art does not teach "the sealed bag originally containing a dosed amount of a soluble sterile product in powder form." Here again, appellants is mistaken in that at least Herbert makes specific mention to the order in which the components are introduced (see at least col. 2, lines 37-61) and makes it clear that the powder is "first" and that the "aqueous solution or carrier solution is then filled." Appellants further present figure 3 to establish that the "structure itself differs from the teachings in both Sutry and Herbert", yet emphasizes this "as a non-limiting example". Thus, begging the question of what scope is being argued.

Appellants argues details not recited in the claims

Appellants continue by providing a detailed description of the structure of the compartments disclosed by Sutry and Herbert, and follows with an initial conclusion (page 7, 1st paragraph). Again, the examiner must emphasize that the claims do not limit the scope to restrictions to compartmentalization, nowhere in the claims is the term "consisting of" mentioned, and it is clear that appellants

is at least arguing structure not recited in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Prior art discloses partially filled bag

Appellants' assertion, that the limitations of partially filling the bag and providing a bag with a capacity greater than the volume of the solution were improperly dismissed, is unfounded. It is clearly addressed by the outstanding rejection and in the depth believed to be necessary to establish a prima facie case of obviousness. The examiner did not believe that the obviousness of leaving room in a bag for the contents to slosh back and forth in, so as to permit a more homogeneous mixture, would require a lengthy explanation. This is especially true in light of the disclosures of Sutry and Herbert, at least as illustrated by the figures that clearly show a partially filled bag and a bag with a capacity greater than the volume of the solution (see fig. 1 of Sutry, and see at least figs. 1-4 of Herbert).

Contrary to appellants' assertion beginning on page 8, 17th line, that in Sutry and Herbert "the bags are initially completely filled", for which absolutely no evidence has been provided, the figures of Sutry and Herbert clearly depict free space in the bags. Even after the soluble powder is incorporated into the

solution it is unlikely to significantly increase the volume of the solution. This is particularly true of a "soluble" powder, as recited in the claims. As with adding sugar to tea; a spoon full of sugar does not significantly increase the volume of the water in the cup. In addition, attention is directed to at least figure 4 of Sutrym, which depicts the powder tablet immersed into the solvent without any significant change to the free space available at the top of the bag. Appellants' allegation (page 8, 1st paragraph, of the Brief) that the only teaching and suggestion is appellants' own disclosure is unfounded.

More details not recited in the claims

In the second and third paragraphs on page 8 of the Brief, appellants again argue features not recited in the claims. Nowhere in the claims is there any mention of varying quantities of soluble product to be placed in the bag. In fact, the only mention remotely related is the claimed "predetermined concentration of the sterile product." The "further adjustments" mentioned in the Brief are not recited in the claims.

Former rejection not relevant to issues at hand

In the last paragraph on page 8 of the Brief, appellants raise a previous rejection and the prior art utilized therein. It should be noted that the

abandonment of the previous rejection was necessitated by appellants' amendments to the claims.

Partial filling and details not claimed revisited

On page 9 of the Brief, appellants again state that the prior art references "disclose completely filling a bag", but fails to recognize the clear indication to the contrary as at least illustrated in the figures of the prior art and inexplicably omits any citing to support appellants' alleged statement of fact.

On page 10 of the Brief, appellants again discuss the merits of "allowing different amount of powder to be initially placed in the bag" of which there is no mention in the claims.

Sequential order revisited

On page 11 of the Brief, appellants' focus on claims 12-25 begins with a return to the previously argued issue of the sequential order in which the contents of the bag are introduced. As discussed above, it would be readily apparent from a cursory glance at the illustrations of Sutry and Herbert that the compartment mentioned by appellants constitutes a part of the bag and thereby contained therein. In addition, Herbert makes specific mention to the order in which the components are introduced (see at least col. 2, lines 37-61) and makes

it clear that the powder is "first" and that the "aqueous solution or carrier solution is then filled."

Prior art discloses individual dose sizes

As regards the limitation of removing individual dose sizes from the bag, it would not require stretching the prior art teaching to state that removal of the entire contents may constitute an individual dose size. As for example the entire contents of an IV bag containing a saline solution and administered to a dehydrated patient. As broadly claimed, this alone reads on the limitation.

Gilford reference is analogous to Sutrym and Herbert

In response to appellants' argument that Gilford is nonanalogous art, it has been held that a prior art reference must either be in the field of appellants' endeavor or, if not, then be reasonably pertinent to the particular problem with which the appellants was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, it should be clear that Gilford is in the field of appellants' endeavor as both involve the field of medicine and more specifically sterile containment. Further, it is apparent that the particular problem with which the appellants were concerned is the removal of the contents of the bag. Clearly Gilford satisfies both requirements. In response to appellants'

assertion that Gilford does not specifically disclose a bag that mixes a powdery substance with a solvent, the examiner would point out that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, Gilford clearly states that "the specific direction toward which the invention is pointed is the provision of novel containers for processing and holding liquid samples" (col. 1, lines 44-47).

Appellants' assertion that Gilford is not directed to storing a solution that is to be applied to a patient in dosages is not relevant as such was not claimed. Again and again, appellants persist in arguing limitations not recited in the claims. There is absolutely no mention in the claims of applying anything to a "patient."

Optimum or workable ranges involves only routine skill in the art

In traversing the rejection of claims 7,10,18,19,23, and 25 appellants again alleges, in the face of clear illustrations in the prior art figures to the contrary, that Sutrym and Herbert require completely filling the bag. Based on this contrary and unsubstantiated assertion appellants allege that the claimed range would not be a matter of discovering the optimum or workable ranges involving only routine skill in the art as established by the court of *In re Aller*.

Since appellants' basic premise is erroneous, it follows that the conclusion is faulty as well.

Applied combination makes obvious multiple single doses

Lastly, appellants assert that claims 8, 11, 13, 15, 17, 21, and 24 further distinguish over the applied art because they require "multiple single doses." As discussed above, Gilford is analogous as it satisfies the test set forth by the court of *In re Oetiker* by being both in the field of appellants' endeavor and is reasonably pertinent to the particular problem with which the appellants was concerned. Further, there appears to be no question as Gilford's teaching of multiple doses, as appellants have emphatically argued that Gilford does not teach a "single dose" (page 13, 5th line, of the Brief). Accordingly, it is purported that the above claims are indeed made obvious by the combination of Sutry or Herbert in view of Gilford.

Conclusion

Contrary to appellants' assertions, the examiner did not arbitrarily dismiss any of the claimed limitations. The prior art relied upon discloses bags containing soluble sterile powder, a sequence of placing the powder in the bag prior to the solvent, partially filled bags, and individual dose sizes. Further, the individual prior art references of the combination relied upon are analogous and

makes obvious withdrawing multiple individual doses. And lastly, the claimed range involves routine skill in the art. Accordingly, it is purported that each and every element recited in the claims is made obvious by the combination of Sutrym or Herbert in view of Gilford.

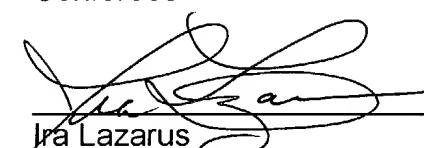
For the above reasons, it is believed that the rejections should be sustained.

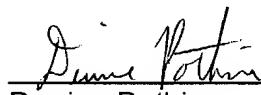
Respectfully submitted,


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July 19, 2004

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